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| APPLICATION NO. | FILI | NG DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|------------|--------------|----------------------|-------------------------|------------------|--|
| 09/810,872 | 03/16/2001 | | Peter Zhu | JOHNA.058A | 7471 | |
| 20995 | 7590 | 03/28/2003 | | • | | |
| | | S OLSON & BE | EXAMINER | | | |
| 2040 MAIN FOURTEEN | TH FLOOF | ₹ | CROSS, LATOYA I | | | |
| IRVINE, CA | 92614 | | | ART UNIT PAPER NUMBER | | |
| | | | | 1743 | : | |
| | | | | DATE MAILED: 03/28/2003 | 5 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|---|--|---|--------------|--|--|--|--|
| | | Application No. | Applicant(s) | | | | | |
| , | • | 09/810,872 | ZHU ET AL | | | | | |
| Office Action Summary | | Examiner | Art Unit | | | | | |
| | | LaToya I. Cross | 1743 | | | | | |
| Period for | Th MAILING DATE of this communication app | ars on the cover sheet w | ith the correspond nce addre | SS | | | | |
| A SHC THE M - Extens after S - If the p - If NO p - Failure - Any re | DRTENED STATUTORY PERIOD FOR REPLY IAILING DATE OF THIS COMMUNICATION. Sions of time may be available under the provisions of 37 CFR 1.13 (K) (6) MONTHS from the mailing date of this communication. Deriod for reply specified above is less than thirty (30) days, a reply be to reply within the set or extended period for reply will, by statute, ply received by the Office later than three months after the mailing I patent term adjustment. See 37 CFR 1.704(b). | 66(a). In no event, however, may a within the statutory minimum of thin will apply and will expire SIX (6) MOI cause the application to become A | reply be timely filed ty (30) days will be considered timely. NTHS from the mailing date of this comm BANDONED (35 U.S.C. § 133). | unication. | | | | |
| Status | | | | | | | | |
| 1)⊠ — | Responsive to communication(s) filed on 16 M | | | | | | | |
| 2a) <u></u> | , | is action is non-final. | | | | | | |
| 3)□ Dispositio | Since this application is in condition for allowated closed in accordance with the practice under the conditions. | ince except for formal ma Ex parte Quayle, 1935 C | ntters, prosecution as to the n D. 11, 453 O.G. 213. | nents is | | | | |
| · | Claim(s) | n the application | | | | | | |
| • | 4a) Of the above claim(s) <u>15-23 and 25-29</u> is/are withdrawn from consideration. | | | | | | | |
| | Claim(s) is/are allowed. | | | | | | | |
| i | ☐ Claim(s) <u>1-7,10-14,30 and 32</u> is/are rejected. | | | | | | | |
| · _ | Claim(s) is/are objected to. | | | | | | | |
| • | Claim(s) <u>1-7,10-23 and 25-32</u> are subject to re | striction and/or election r | equirement. | | | | | |
| • | on Papers | | | | | | | |
| 9)□ T | he specification is objected to by the Examine | r. | | | | | | |
| 10)□ T | The drawing(s) filed on is/are: a)□ accep | oted or b) objected to by | the Examiner. | | | | | |
| | Applicant may not request that any objection to the | | | | | | | |
| 11)□ T | he proposed drawing correction filed on | | disapproved by the Examiner. | | | | | |
| | If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| <i>,</i> — | he oath or declaration is objected to by the Ex | aminer. | | | | | | |
| - | nder 35 U.S.C. §§ 119 and 120 | | | | | | | |
| • | Acknowledgment is made of a claim for foreigr | n priority under 35 U.S.C. | § 119(a)-(d) or (f). | | | | | |
| a)[_ | ☐ All b)☐ Some * c)☐ None of: | | | | | | | |
| | 1. Certified copies of the priority document | | | | | | | |
| | 2. Certified copies of the priority document | | | | | | | |
| | 3. Copies of the certified copies of the priorapplication from the International Bure the attached detailed Office action for a list | reau (PCT Rule 17.2(a)). | | age | | | | |
| 14)∐ A | cknowledgment is made of a claim for domesti | c priority under 35 U.S.C | . § 119(e) (to a provisional ap | oplication). | | | | |
| | ☐ The translation of the foreign language procedures and the company of the foreign language procedures the company of the co | | | | | | | |
| Attachment | | | | | | | | |
| 2) Notice | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) 2 | 5) Notice of | Summary (PTO-413) Paper No(s). Informal Patent Application (PTO-1 | | | | | |
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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 10-14, 30 and 32, drawn to a method for determining aldehydes, classified in class 436, subclass 128.
 - II. Claims 15-23, 25-29 and 31, drawn to a liquid measuring device, classified in class 73, subclass 149.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP \$806.05(h)). In the instant case, the device may be used to measure a liquid other than those containing aldehydes.
- 3. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
- During a telephone conversation with Che Chereskin on March 20, 2003 a provisional election was made without traverse to prosecute the invention of group I, claims 1-7, 10-14, 30 and 32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-23, 25-29 and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-7, 11, 12, 14 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,471,055 to Opp.

Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration. The predetermined concentration of aldehyde is the point of interest of aldehyde. The method for determining whether aldehyde is present in a predetermined concentration taught by Opp comprises mixing the test sample with a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde, and detecting any visual formation of a second reaction product, as recited in claim 1 (col. 14, lines 7-41). The aldehydes to be tested are those used in disinfecting systems (in germicidal capacities) having at least one —CHO moiety, which includes glutaraldehyde, phthaldehyde, and formaldehyde, as recited in claims 6 and 7. The first reaction system includes reactants which

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form a colorless derivative of aldehyde, such as hydroxylamine or hydrazine, as recited in claim 5 (col. 4, lines 15-30). The second reaction system includes reactants that form aldehyde derivatives which are visually distinguishable from the first reaction products, such as amino acids, including glycine and lysine, as recited in claims 2-4 (col. 4, lines 38-55). Opp teaches that the first reaction products are colorless, as recited in claim 10 (col. 4, lines 15-17, col. 14, lines 42-43). With respect to claim 11, Opp teaches that the amount of first reaction system completely transform the amount of aldehyde equal to the predetermined amount, while the second reaction system provides a visual color where the amount of aldehyde exceeds the predetermined amount. Where the amount of aldehyde is less than the predetermined amount (1% for disinfecting processes), it would be inherent that no color would form since there would not be an excess amount of aldehyde to react in the second reaction system. With respect to claim 12, each of examples I-IX of Opp teaches providing a fixed volume of sample (0.1-1 milliliter) to which the reactants are added. Further, with respect to claim 14, Opp teaches that the fixed volume of test sample is added to a 7 cc reaction container (measuring device), where the reaction container the first reaction system reagents (hydroxylamine or hydrazine).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Opp '055.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Opp in view of US Patent 4,703,763 to McAlister et al.

The disclosure of Opp is described above. Opp fails to teach loading a fixed volume of test sample into a measuring device having a liquid impermeable membrane.

McAlister et al teach a device for sample a pre-set volume of test sample. The device is a syringe-type measuring device having a plug element (filter) arranged to be air-permeable, but liquid impermeable. This allows enough fluid sample to be up taken into the syringe and then allow the fluid flow to stop when the predetermined amount is taken in. See col. 1,1 ines 41-59. It would have been obvious to one of ordinary skill in the art to use the device of McAlister et al to measuring an exact amount of test sample in carrying out the method of Opp. Such will prevent using excess sample. Since it is important that the amount of reagents in the method of Opp be exact for the amount of sample, using the device of McAlister et al will alleviate false positives due to incorrect reagent to sample ratios.

Therefore, for the reason set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Opp and McAlister et al.

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11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,521,376 to Witonsky et al in view of US Patent 6,436,716 to Wu.

Witonsky et al teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value. The method tests for sufficient glutaraldehyde amounts in a disinfecting solution. The method involves contacting a test sample with a test strip impregnated with a sulfite compound and an amino acid compound. The sulfite compound is sodium sulfite (col. 2, line 24). The amino acid is glycine (col. 2, line 27). The method by which excess glutaraldehyde is to be determined is explained in Wu. Glutaraldehyde reacts with sulfite to form a sulfite addition product, which reacts with glycine to form sodium glycinate. Excess glutaraldehyde reacts with sodium glycinate to form a colored product. Thus, the sulfite serves as a first reactant to react with the carbonyl group in the aldehyde and glycine serves as the second reactant to react with remaining aldehyde in the sample that is unreacted. See col. 2, lines 39-52.

Witonsky et al teaches using sodium sulfite, but fail to teach using sodium bisulfite. Wu teaches that both sodium sulfite and sodium bisulfite are effective in processes for determining the presence of aldehydes (col. 1, line 65 – col. 2, line 12). It would have been obvious to one of ordinary skill in the art to substitute sodium sulfite in Witonsky et al for sodium bisulfite, since both are known in the art to be suitable in determining the presence of aldehydes. See MPEP 2144.06.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Witonsky et al and Wu.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

lic March 24, 2003

> Supervisory Patent Examiner Technology Center 1700